



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 2, 2016

Tornier SAS
Mrs. Magalie Hennequin
Regulatory Project Manager
161 rue Lavoisier
38334 Montbonnot Saint Martin
FRANCE

Re: K132285

Trade/Device Name: Aequalis Reversed Shoulder Prosthesis
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS
Dated: November 21, 2013
Received: November 22, 2013

Dear Ms. Hennequin:

This letter corrects our substantially equivalent letter of December 5, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132285

Device Name: *Aequalis Reversed Shoulder Prosthesis*

Indications For Use:

Cemented Aequalis Reversed prosthesis:

It is indicated for patients with a functional deltoid muscle as a total shoulder replacement for the relief of pain and significant disability following arthropathy associated with the massive and non-repairable rotator cuff-tear. This device is also indicated for the prosthetic revisions with massive and non-repairable rotator cuff-tear. Only the humeral components are for cemented use. The glenoid implant is anchored to the bone with 4 screws and is for non-cemented fixation.

When during the primary surgery the glenoid bone stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemi-prosthesis adaptor and the union screw can be adapted to the humeral components in order to transform the Aequalis Reversed prosthesis into a non-reversed hemi-prosthesis.

When, in case of revision of a Aequalis Reversed prosthesis, the glenoid bone stock appears to be insufficient to again implant a base plate and a sphere of Aequalis Reversed range, the use of the hemi-prosthesis adaptor and the union screw allows for the transformation of the Aequalis Reversed prosthesis into a non-reversed hemi-prosthesis in order to avoid the revision of the humeral components.

Uncemented Aequalis Reversed prosthesis:

It is indicated for patients with a functional deltoid muscle as a total shoulder replacement for the relief of pain and significant disability following arthropathy associated to massive and non-repairable rotator cuff-tear. This device is also indicated for the prosthetic revisions with massive and non-repairable rotator cuff-tear. The humeral components are for non-cemented use. The glenoid implant is anchored to the bone with 4 screws and is for non-cemented fixation.

When during the primary surgery the glenoid stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemi-prosthesis adaptor and the union screw can be adapted to the humeral components in order to transform the Aequalis Reversed prosthesis into a non-reversed hemi-prosthesis.

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Prescription Use **X**
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510 (k) Summary of Safety and Effectiveness information Traditionnal 510(k) Premarket Notification – Aequalis Reversed Shoulder Prosthesis

Regulatory authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1) Device name

Trade name: *AEQUALIS Reversed Shoulder Prosthesis*
Common name: Shoulder Prosthesis
Classification name: Shoulder joint metal/polymer semi-constrained cemented prosthesis

2) Submitter

TORNIER SAS
 161 rue Lavoisier
 38330 Montbonnot Saint Martin- France
 Registration Number: 3000931034

DEC 05 2013

3) Company contact

Tornier
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4) Classification

Device class: Class II
Classification panel: Orthopedic
Product code: KWS

5) Equivalent / Predicate device

Aequalis Reversed Shoulder Prosthesis, TORNIER SAS, K030941, K050316, K061439, K081059, K100142
Aequalis Ascend Flex Shoulder, TORNIER SAS, K122698
Reverse Shoulder Prosthesis, DJO SURGICAL, K041066, K051075, K092873

6) Device description

The *Aequalis Reversed Shoulder Prosthesis* is intended to be used to relieve pain and significant disability following massive and non repairable cuff-tear associated to arthropathy and following massive cuff-tear arthropathy. In this case, the rotator muscles of the shoulder (supraspinatus, infraspinatus, teres minor and long head of the biceps) are no more useful for mobility, and only the deltoid (for abduction and external rotation) and the subscapularis (for internal rotation) are functional.

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Therefore, the usual goal of such surgery is to restore the shoulder joint to facilitate its working condition and to reduce or eliminate pain. The *Aequalis Reversed Shoulder Prosthesis* is intended to accomplish these goals. Its reversed design allows to medialize the center of rotation of the shoulder, lengthening the deltoid muscle lever arm.

The *Aequalis Reversed Shoulder Prosthesis* is a semi-constrained system composed of a humeral and a glenoid parts.

The present device modification submission consists in the addition of glenoid base plates with central threaded post and a new coating.

7) Materials

The glenoid base plate is manufactured from Titanium alloy.

The TiPS coating conforms to the ASTM standard F 1580.

The coating is performed by Eurocoating or APS according to their Master File MAF1760 (for Eurocoating) and MAF 628 (for APS).

8) Indications

Cemented Aequalis Reversed prosthesis:

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9) Summary of technological characteristics

Main features or system characteristics		Aequalis Reversed II Shoulder System (new components)	Aequalis Reversed II Aequalis Reversed II Shoulder System	Aequalis Ascend:flex	Reverse Shoulder Prosthesis
Material	Glenoid base plate	Ti6Al4V	Ti6Al4V or Ti6Al4V + HA	Ti6Al4V	Alloy titanium
Standard	Glenoid base plate	ISO 5832-3	ISO 5832-3	ISO 5832-3	-
Coating material	Glenoid base plate	TiPS Coating	Hydroxylapatite		
Coating standard	Glenoid base plate	ASTM F 1580	ASTM F 1185	ASTM F 1580	-
Method of fixation	Glenoid component	Uncemented	Uncemented	Uncemented	Uncemented
Glenoid base plate diameter		25mm or 29mm	25mm or 29mm	NA in reversed configuration **	
Post	Post design	Threaded post	Press fit post	NA in reversed configuration **	Threaded post
	Post length	20 mm to 50mm	15mm or 25mm	NA in reversed configuration **	
	External diameter	9.5mm +/- 0.05mm	8.3mm +/- 0.05mm	NA in reversed configuration **	
	Diameter of bottom of the thread	6.5mm +0.35/-0.05mm	NA	NA in reversed configuration **	
Terminal sterilization		Yes	Yes	Yes	Yes
Manufacturer		Tornier	Tornier	Tornier	DJO
K-number		Pending	K030941 K050316 K061439 K081059* K100142	K122698	K041066 K051075 K092873

The indication for use, the materials, the manufacturing principle and the sterilization process are similar to the cleared Aequalis Reversed II glenoid base plate.

The design, the coating and the method of fixation of the pending Aequalis Reversed II glenoid base plate is substantially similar to the predicates.

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Two technological features are different for the new components of the Aequalis Reversed Prosthesis from the predicates:

- The dimension of the post,
- The design of the post.

The new length of the post length allows to the surgeon to choose the length adapted to the patient's morphology (bone volume) so that the post rest on the bone.

In comparison of the recommended drilled hole diameter of the pending Aequalis Reversed base plate and the predicate, we can see that the pending Aequalis Reversed base plate is equivalent with the predicates concerning the risk of glenoid's fracture.

To demonstrate that the anchorage of the base plate on the bone is equivalent independently of the post design a pull out testing was conducted on the new Aequalis Reversed II glenoid base plate and the cleared Aequalis Reversed II glenoid base plate.

10) Non-clinical testing

Pull out testing and cadaver testing was performed.

The aim of pull out testing (E1586) is to show the equivalence between the new Aequalis Reversed base plates and the cleared models independently of the post design.

Posts of glenoid base plate (pending and cleared) are impacted in the same foam bloc in several configurations.

To demonstrate the equivalence between the new glenoid base plate and the cleared glenoid base plate the resistance in Pull-out has to be equivalent.

The aim of cadaver testing is to ensure proper use of instruments and implants.

The result shows that primary fixation has been achieved without scapular fracture or other major peri-operative complications.

11) Substantial equivalence conclusion

Based upon this comparative study, substantial equivalence of the new glenoid base plate of the Aequalis Reversed II Shoulder Prosthesis to the cleared glenoid base plate of the Aequalis Reversed II Shoulder Prosthesis can be demonstrated on the following grounds, according to the FDA's Guidelines for Substantial Equivalence Decision Making Process:

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- The new glenoid base plate of the Aequalis Reversed II Shoulder Prosthesis are compared to the predicate devices.
- The new glenoid base plate of the Aequalis Reversed II Shoulder Prosthesis have the same intended use as the cleared glenoid base plate of the Aequalis Reversed II Shoulder Prosthesis.
- Major technological characteristics are equivalent between the new glenoid base plate of the Aequalis Reversed II Shoulder Prosthesis and the predicate devices:
 - Equivalence of general features
 - Equivalent means of fixation
 - Equivalent materials

Therefore, in the light of the above information, the new glenoid base plate of the Aequalis Reversed II Shoulder Prosthesis are found to be equivalent to the predicate devices.

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